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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,258	01/18/2007	Guy Vergnault	28069-618-NATL	3154

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EXAMINER	
LOVE, TREVOR M	
ART UNIT	PAPER NUMBER
1611	
MAIL DATE	DELIVERY MODE
01/18/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,258	VERGNAULT ET AL.	
	Examiner	Art Unit	
	TREVOR M. LOVE	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/14/2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-17* is/are pending in the application.

4a) Of the above claim(s) *9-11 and 15-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-8 and 12-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made to Applicant's response filed 10/14/2010. Attention is drawn to the Petition decision mailed by the Office 11/23/2010.

Claims 1, 2, 4-17 are pending.

Claims 9-11 and 15-17 are withdrawn as being drawn to non-elect groups and/or species. See MPEP 818.01 and 818.02(a) with regard to election by original presentation.

Claims 1, 2, and 4-14 are currently under consideration.

No claims are identified as being amended.

Claims 15-17 are newly added.

Withdrawn Rejections and/or Objections

The objection to the specification is withdrawn upon further consideration of proper treatment of international applications.

Maintained Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Spence et al (U.S. Patent number 3,146,169, Patent issued Aug. 25, 1964).

Spence teaches a tablet with an inert portion that surrounds an active portion (see entire document, for instance column 1, lines 33-36 and Figure IV). Said inert portion and said active portion can comprise the core. Said core is coated by a further outer layer (see entire document, for instance Figure IV and column 3, lines 35-36). Said inert portion comprises components such as barium sulfate or aluminum silicate (see column 1, lines 49-56), this reads on **instant claims 1 and 4**.

Response to Arguments

Applicant argues in the remarks filed 10/14/2010 that Spence teaches that the medicated portion covers part if not all of the inert portion, which is the opposite of the instant invention. Applicant's argument is not found persuasive since, as cited above, Spence teaches an inert portion that surrounds an active portion (see entire document, for instance column 1, lines 33-36 and Figure IV). Therefore, since the reference supports the Examiner's position, Applicant's argument is not found persuasive. Applicant further argues that Spence fails to teach the aluminum silicate or barium sulphate is in the active containing core. Applicant's arguments are not found persuasive since for example, components 1 and 2 of Figure IV can be deemed the "core", and therefore, the core would contain the aluminum sulphate and active component. It is noted that in the absence of a clear definition, the core is being interpreted as a portion of the tablet which is covered in some way (i.e. an interior core). It is also noted that the instant claims do not in any way identify the orientation of the

components within the instant core, therefore, an inner core with an outer core around said inner core reads on the instantly claimed core. Applicant further argues that Spence does not teach an excipient that is opaque to x-rays, Applicant's argument is not found persuasive since first, it is noted that said limitation is an intended use of the tablet, and second, since barium sulphate and aluminum silicate are taught as being present in the composition of Spence, and therefore, said "intended use" would also have necessarily occurred.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence et al (U.S. Patent number 3,146,169, Patent issued Aug. 25, 1964).

Spence teaches a tablet with an inert portion that surrounds an active portion (see entire document, for instance column 1, lines 33-36 and Figure IV). Said inert portion and said active portion can comprise the core. Said core is coated by a further outer layer (see entire document, for instance Figure IV and column 3, lines 35-36). Said inert portion comprises components such as barium sulfate, aluminum silicate, or calcium silicate (see column 1, lines 49-56), this reads on **instant claims 1 and 4**. Spence further teaches that aluminum silicate can be present as, for example, 2.8% of the composition (see Example 7 (b) in context of example 1), note that 2.8% is "about" 1.75%, this reads on **instant claim 5**. The claims of Spence directly state that both barium sulphate and aluminum silicate can be utilized as the inert portion (see entire document, for instance, claims 4 and 6). It is further noted that in Example 7(e) in the context of Example 5, the main inert component (calcium silicate) is present as about 1.3% of the composition.

Spence fails to directly teach the instant amount of excipient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize barium sulphate or aluminum silicate in the place of the calcium silicate in example 7(e) in the context of example 5. One would have been motivated to do so since an express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). "Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301.).

Response to Arguments

Applicant's argues in the remarks filed 10/14/2010 that the tablet of Spence, which Applicant identifies as "a multi-layered tablet where the medicated portion is surrounded by an inert portion and two outer layers" (see remarks, page 8, last paragraph), differs from the instant invention. Applicant argues that Spence adds additional layers for protection and that the inner core does not comprise all the components required by the instant claims. Applicant's argument is not found persuasive since, the core, for example in Figure IV can be defined as portions identified as 1 and 2 contains the components required in the instant claims. Therefore, Applicant's arguments are not found persuasive.

Claims 2, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence et al (U.S. Patent number 3,146,169, Patent issued Aug. 25, 1964) as applied to claims 1 and 4-6 above, and further in view of Thurn-Müller et al (U.S. Patent number 5,310,578, Patent issued May 10, 1994).

The teachings of Spence are set forth above under the discussion of claims 1 and 4-6.

Spence further fails to teach the presence of red iron oxide.

Thurn-Müller teaches that red iron oxide, aluminum silicate and calcium silicate are well known examples of pigments (see entire document, for instance, column 2, lines 44-58).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize red iron oxide with the aluminum silicate, barium sulphate, and/or calcium silicate of Spence. One would have been motivated to do so since it is known to combine known products which are performing their known function to arrive at a third composition for the exact same purpose. There would be a reasonable expectation of success since Thurn-Müller teaches that red iron oxide, aluminum silicate, and calcium silicate are known pigment components, and Spence teaches that aluminum silicate, barium sulphate, and calcium silicate are functionally equivalent and can be utilized in combination. It is noted that MPEP 2144.05 states: ""It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been

individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

Response to Arguments

Applicant argues in the remarks filed 10/14/2010 that Thurn-Müller does not cure the deficiencies of Spence identified above, and therefore, the rejection should be withdrawn. Applicant's arguments are not found persuasive since Applicant's arguments above are not found persuasive.

Claims 7, 8, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence et al (U.S. Patent number 3,146,169, Patent issued Aug. 25, 1964) as applied to claims 1 and 4-6 above, and further in view of Guglielmotti et al (U.S. Patent number 6,020,356, Patent issued Feb. 1, 2000).

The teachings of Spence are set forth above under the discussion of claims 1 and 4-6 wherein it is further noted that Spence teaches that "[t]he medicament in the medicated portion may be any desired medicament" (see column 2, lines 32-33).

Spence further fails to teach the presence of prednisone, prednisolone, or methylprednisolone. Spence further fails to directly teach the dose of said prednisone.

Guglielmotti teaches the treatment of several conditions including autoimmune hepatitis, type 1 diabetes, and systemic lupus crythematosus with a combination of bindarit and immunosuppressant (see entire document, for instance column 2, lines 12-

18). Guglielmotti teaches the immunosuppressant is typically prednisolone, methylprednisolone, or prednisone (see entire document, for instance, column 2, lines 5-11). Guglielmotti specifically identifies prednisone as being useful, and exemplifies a dosage of 5 mg (see entire document, for instance column 2, lines 48-51 and column 4, lines 1-3), wherein the composition of Guglielmotti can be in the form of coated tablets which comprise excipients and coloring agents (see entire document, for instance column 2, lines 58-62).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the medicaments, bindarit and prednisone (5mg), as the medicaments of Spence. One would have been motivated to do so since Spence teaches that the medicament can be any desired medicament, wherein Guglielmotti teaches clear motivation for why one would desire bindarit and prednisone which includes the numerous diseases that can benefit from the delivery thereof. There would be a reasonable expectation of success in the use of the medicaments of Guglielmotti in the delivery system of Spence since Spence teaches that any desired medication can be utilized, wherein further Guglielmotti teaches that the medicaments of Guglielmotti can be in the form of a coated tablet and can comprise excipients and coloring agents.

Response to Arguments

Applicant's argues in the remarks filed 10/14/2010 that Guglielmotti does not cure the deficiencies of Spence identified above, and therefore, the rejection should be withdrawn. Applicant's arguments are not found persuasive since Applicant's arguments above are not found persuasive. Applicant further argues that Guglielmotti

does not refrain one from adding to the non-medicated inert coating a colorant, which would defeat the purpose of the instant invention, therefore, the teachings of Guglielmotti would result in a different tablet than the instant invention. Applicant's arguments are not found persuasive since first, it is noted that the instant invention does not require the absence of colorant in any portion of the composition, and second, the reliance of Guglielmotti is for the teaching of the medicaments, wherein it is noted that Guglielmotti teaches the medicaments are known to be able to be in compositions with excipients and coloring agents. Therefore, the teaching relied upon from Guglielmotti is directed to the medicament, not excipients. Therefore, Applicant's arguments are not found persuasive.

Conclusion

No claims allowed. All claims rejected. No claims objected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/David J Blanchard/
Primary Examiner, Art Unit 1643